HDMA
Healthcare Distribution
Management Association

EXHIBIT 2
DATE 2-14-07
HB 536

February 14, 2007

The Honorable Arlene Becker
Montana House of Representatives
P.O. Box 201706
Helena, MT 59620-1706

Dear Representative Becker:

On behalf of the Healthcare Distribution Management Association (HDMA) and its distributor members serving Montana, I respectfully submit the enclosed comments to House Bill 536. I was hoping to testify today, February 14, at the Human Services Committee hearing, but unfortunately am unable to get to Helena due to severe weather and flight cancellations. I hope that you will consider these comments in my absence.

HDMA commends you for your efforts in this area, as we are actively working in states across the country to identify and implement effective approaches to deter and prevent the introduction of counterfeit and adulterated prescription drug products in the nation's pharmaceutical supply chain.

Each element of the supply chain – manufacturers, distributors, and pharmacies – has a critical role to play in implementation of these approaches. While there is much common ground across the supply chain, this is a complex issue and it is essential that legislatures and regulatory bodies consider the implications of their proposals not only on prescription drug safety, but also on operational issues that may affect consumer access to necessary medications. HDMA's comments, redlined in the original language, address several issues. I have attempted to summarize our priority issues below and I believe the remainder of our suggestions are technical in nature.

Manufacturer Definition

This change was made in order to provide additional clarification, in particular in cases where the manufacturer might not meet the "simple" definition, but is clearly the true originator of the prescription drug. In today's pharmaceutical market, there are many iterations of the manufacturing process that may not have existed in the past, especially for biologics and generics. In order to ensure that access to these important medicines is not adversely affected, and to allow for innovation in the marketplace, we support expanding the definition of manufacturer as reflected in our edits.

Normal Distribution Channel

HDMA believes that inclusion of a transaction path that goes from an Authorized Distributor of Record (ADR) to another ADR to an office based provider (e.g., physician) will both keep the normal supply channel limited

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enough to deter the entrance of counterfeits and ensure that small physician practices are able to continue to serve their patients appropriately.

Manufacturer Exemptions

While HDMA recognizes the critical role of the manufacturer in the supply chain, we do not advocate for a blanket exemption for manufacturers from state requirements aimed at protecting the public. The manufacturer community is as diverse as any other and they collectively play an important role in protecting prescription drug consumers. If a manufacturer is engaging in business in a state, and if they are engaging in wholesale distribution activities, their facilities should be subject to the same scrutiny as other members of the supply chain.

Inspections

As a condition of licensure, HDMA advocates for inspections of distribution centers by state regulatory authorities. While we are sympathetic to state agencies with limited resources, particularly in performing out of state inspections, we strongly believe that this is an important state function that should be left under the control of the state agency. In situations where a state is unable to perform inspections of non-resident facilities, we hope to encourage neighboring states to institute similar rigorous inspection and licensure polices. HDMA supports recognition of a variety of methods to ensure that a facility has been properly vetted and s meeting all federal and state requirements. In this regard, we support recognition of a resident-state inspection or a license in good standing, in the spirit of both preserving patient safety and encouraging interstate commerce.

Designated Representatives

HDMA fully supports the concept of the "designated representative" to ensure compliance and proper management of distribution facilities. However, we urge you to amend the "continuing education" requirement and instead require distributors to provide appropriate training for their designated representative employees. Unlike pharmacists and other healthcare professionals that the Board of Pharmacy may be very familiar with, designated representatives most often are *distribution* managers or experts. Typically, these professionals will be trained by their employers on a regular basis and are responsible for understanding compliance obligations under state and federal laws governing the distribution of pharmaceutical products and controlled substances. In almost every case, these individuals are not pharmacists, and there are no current Board of Pharmacy or Pharmacy Association programs to date that are designed for this area of expertise. We recommend amending this language and simply requiring that the designated representative undergo continuing training in relevant subject matter.

Track and Trace/Electronic Pedigree

HDMA advocates for development of a track and trace system that supports pedigree and tracks the path of a drug from its creation through the supply chain until it is ultimately dispensed to the patient. This type of system is under development but may not be widely available for several years. In the interim, HDMA supports additional regulatory controls such as stronger licensure laws, increased penalties, and use of pedigree as a safety mechanism in those instances where drugs are at the highest risk – outside the normal distribution channel.

We believe that tracking technologies such as RFID have the most promise for use in this way by the supply channel. However, any such tracking mechanism must originate at the manufacturer – at the product's inception - in order to ensure that there are no gaps in the supply chain that might invite counterfeiters or diverters of prescription medicines.

Enforcement/Prohibited Acts/Penalties

When a manufacturer is functioning in the capacity of a wholesale distributor (e.g., warehousing and shipping drugs), there is no logical reason to regulate the manufacturer any differently than a wholesale distributor. Manufacturers have argued that they are already subject to the FDA's Good Manufacturing Practice (GMP) regulations and, therefore, they are already highly regulated. The reality is that the GMP regulations focus on manufacturing practices and not to any significant extent on distribution practices. In addition, the penalties included in the GMP regulations (three years for similar violations) are much weaker than the penalties proposed in this model language (up to fifteen years for violations). HDMA recommends that manufacturers *not* be exempted from the enforcement and prohibited acts language in HB 536.

The changes we suggest to the penalties section of HB 536 recognize the need for harsher penalties for those individuals who intentionally engage in activity related to counterfeit drugs. HDMA believes that penalties should appropriately match the level of illegal activity and the level of intent that accompanies the crime.

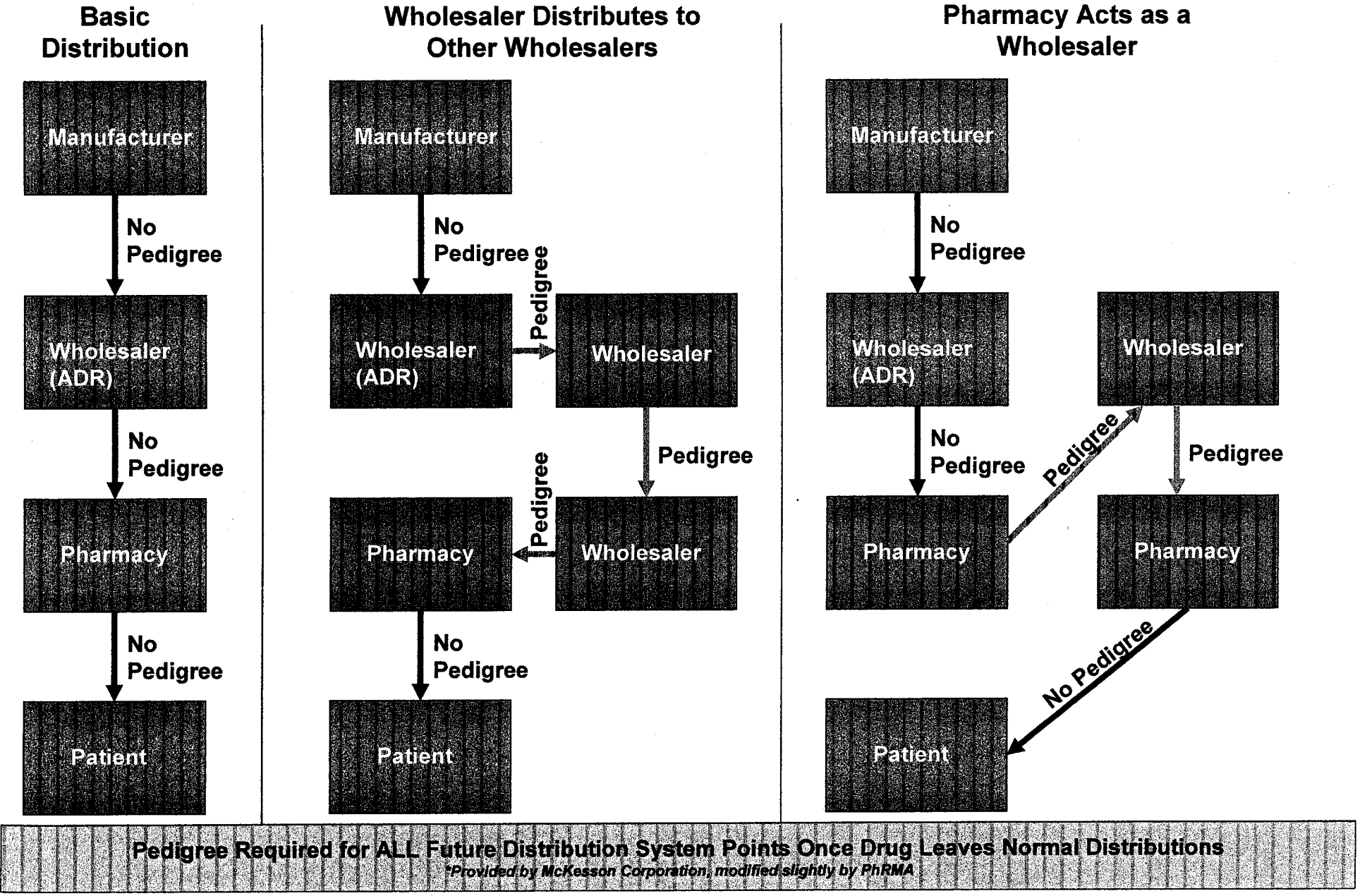
Thank you for your consideration of this important matter. I am available to answer any questions you may have or to provide additional information. Please feel free to contact me at 703-885-0234 or egallenagh@hdmanet.org.

Sincerely,

Elizabeth A. Gallenagh, Esq.
Director, State Government Affairs

cc: Hon. Ron Stoker, Chair, Human Services Cmte.
Ms. Sue O'Connell, LSD
Ms. Starla Blank, Exec. Director, Montana Board of Pharmacy

Passing of a Pedigree:
Basic Normal Distribution v. Outside Normal Distribution



Pedigree Required for ALL Future Distribution System Points Once Drug Leaves Normal Distributions

**Provided by McKesson Corporation, modified slightly by PhRMA*